78. (Newly Added) The host cell of claim 2, wherein said wash is in 0.05 x SSC and 0.1% SDS at 65°C.

79. (Newly Added) The porcine α-1,3 galactosyltransferase of claim 3, wherein said wash is in 0.05 x SSC and 0.1% SDS at 65°C.

80. (Newly Added) The DNA construct of claim 46, wherein the gene, prior to disruption, encodes a porcine α-1,3 galactosyltransferase with an amino acid sequence of SEQ ID NO:10.

81. (Newly Added) The method of claim 51, wherein the gene, prior to disruption, encodes a porcine α-1,3 galactosyltransferase with an amino acid sequence of SEQ ID NO:10.

## REMARKS

Status of the claims

Claims 1-3, 46-51, 67, and 70-81 are pending in this application, claims 78-81 having been added by the above amendment. New claims 78 and 79 are supported by the specification, e.g., at page 7, lines 11-14. New claims 80 and 81 are supported by the specification, e.g., at page 7, line 24 to page 8, line 5, and Example 7. The amendment to claim 1 is supported by the specification, e.g., SEQ ID NO:7 as depicted in the Sequence Listing. The amendments to claims 2 and 3 are supported by the specification, e.g., at page 5, line 18 to page 6, line 14, page 7, lines 11-14, and SEQ ID NO:7 as depicted in the Sequence Listing. The amendment to claim 46 is supported by the specification, e.g., at page 7, line 24 to page 8, line 26 and Examples 7 and 8. No new matter has been added to the application.

Disclosure date of SEQ ID NO:7

The priority of the instant application is more clearly stated in the claim for priority as amended herein.

Applicants' undersigned representative thanks the Examiner and Examiner Deborah Clark for their courtesy in a telephone interview on February 14, 2001. In that interview, Examiner

Clark stated that, provided that Applicants could perfect the declaration filed July 30, 1997, as indicated on page 2, paragraph 2, of the Office Action, SEQ ID NO:7 would be deemed to have been disclosed in the earliest priority document of the instant application, i.e., U.S. Application Serial No. 08/188,607, filed January 27, 1994. The signed declaration enclosed as Exhibit A serves to so perfect the declaration filed July 30, 1997, and thus Applicants respectfully submit that the disclosure date of SEQ ID NO:7 is January 27, 1994.

The 35 U.S.C. §112, second paragraph, rejection

Claims 1-3 stand rejected as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse the rejection.

As indicated in the response filed August 14, 2000, the text of the specification cited in support of "conservative amino acid substitutions" uses the term "minor amino acid variations." (page 6, line 21 to page 7, line 3). Applicants submit that one of skill in the art would understand the latter term to be equivalent to the more commonly used former term and thus to mean amino acid changes within the same group of amino acids, e.g., polar amino acids, hydrophobic amino acids, or positively charged amino acids. The clause "that leave a functional α-1,3 galactosyltransferase catalytic site, membrane anchor domain and stem region" does not serve to define "minor amino acid variations" but adds a functional limitation on variant molecules containing the minor amino acid variations. Moreover, Applicants respectfully submit that if the intended meaning in claim 1 had been that the relevant amino acid change not change the function of the protein, Applicants would not have included the additional limitation "wherein said second polypeptide retains a functional α-1,3 galactosyltransferase catalytic site, a functional membrane anchor domain and a functional stem region," as to have done so would have been redundant.

In light of the above considerations, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

The 35 U.S.C. §102(b) rejection

Claim 1 stands rejected as allegedly being anticipated by Strahan et al., GenEmbl Accession No. L36152 (V2). Applicants respectfully traverse the rejection.

In view of the disclosure date of SEQ ID NO:7 (see above), Applicants submit that the cited reference is not prior art with respect to the present application.

In light of the above consideration, Applicants respectfully request that the rejection under 35 U.S.C. §102(b) be withdrawn.

The 35 U.S.C. §103(a) rejections

(a) Claims 2 and 3 stand rejected as allegedly being unpatentable over Ohgi et al. (X2) in view of Strahan et al. (W2). Applicants respectfully traverse this rejection.

In view of the disclosure date of SEQ ID NO:7 (see above), Applicants submit that Strahan et al., 1995 (W2) is not prior art with respect to the present application.

(b) Claims 46-51, 67, and 70-77 stand rejected as being unpatentable over Sandrin et al., U.S. Patent No. 5,821,117 (A) and Galili, (U2) in view of Strahan et al. (V2) and Hodges et al., U.S. Patent No. 5,527,695 and the effective filing date for the sequence of SEQ ID NO:7 of the present application. Applicants respectfully traverse this rejection.

In view of the disclosure date of SEQ ID NO:7 (see above), Applicants submit that none of Sandrin et al., Strahan et al. (V2) and Hodges et al. is prior art with respect to the present application. Furthermore, Applicants do not acknowledge that Galili et al. is prior art with respect to the present application.

In light of the above considerations, Applicants respectfully request that the rejections under 35 U.S.C. §103(a) be withdrawn.

Attached is a marked-up version of the changes being made by the current amendment.

## CONCLUSIONS

Applicants submit that claims 1-3, 46-51, 67, and 70-81 patentably define the invention. Applicants request that the Examiner reconsider the rejections set forth in the Office Action, and permit the pending claims to pass to allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' undersigned representative can be reached at the telephone number listed below.

Enclosed is a two-month extension of time with the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 4/9/01

Stuart Macphail

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**Version with markings to show changes made**

In the specification:

Page 1, paragraph 1, of the specification has been amended as follows:

[This is a continuation of U.S. application serial no. 08/378,617, filed 01/26/95 (pending). The present application is a continuation-in-part of U.S. Application Serial No. 08/188,607, filed January 27, 1994.] This is a continuation of U.S. Application Serial No. 08/378,617, filed January 26, 1995 (now U.S. Patent No. 5,849,991), which was a continuation-in-part of U.S. Application Serial No. 08/188,607, filed January 27, 1994 (now abandoned).

In the claims:

Claims 1-3, and 46 have been amended as follows:

1. (Thrice amended) A purified and isolated nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of (1) nucleotides 90 -1203 of the porcine nucleic acid sequence [depicted in Figure 4 (] with SEQ ID NO: 7[)], (2) a sequence encoding a porcine polypeptide having α-1,3 galactosyltransferase activity and having the amino acid sequence of SEQ ID NO:10, (3) a sequence that encodes a second polypeptide identical to said porcine polypeptide except for one or more conservative amino acid substitutions, wherein said second polypeptide retains a functional α-1,3 galactosyltransferase catalytic site, a functional membrane anchor domain and a functional stem region, and (4) a sequence complementary to the sequence of (1), (2) or (3).

2. (Amended) A host cell that is transformed with [the] a nucleic acid molecule [of claim 1] comprising a nucleic acid sequence selected from the group consisting of (1) nucleotides 90 -1203 of the porcine nucleic acid sequence with SEQ ID NO: 7, (2) a sequence corresponding to the sequence of (1) within the scope of the degeneracy of the genetic code, (3) a sequence that encodes a porcine polypeptide having α-1,3 galactosyltransferase activity and that hybridizes with a sequence complementary to the sequence of (1) or (2) after a wash at 65°C in a buffer containing 0.1% SDS and SSC at a concentration not greater than 0.5 x, and (4) a sequence complementary to the sequence of (1), (2) or (3).

3. (Amended) A porcine α-1,3 galactosyltransferase encoded by [the] a nucleic acid molecule [of claim 1] comprising a nucleic acid sequence selected from the group consisting of (1) nucleotides 90 -1203 of the porcine nucleic acid sequence with SEQ ID NO: 7, (2) a sequence corresponding to the sequence of (1) within the scope of the degeneracy of the genetic code, (3) a sequence that encodes a porcine polypeptide having α-1,3 galactosyltransferase activity and that hybridizes with a sequence complementary to the sequence of (1) or (2) after a wash at 65°C in a buffer containing 0.1% SDS and SSC at a concentration not greater than 0.5 x, and (4) a sequence complementary to the sequence of (1), (2) or (3).

46. (Twice amended) A DNA construct comprising a disrupted porcine α-1,3 galactosyltransferase gene, [wherein the gene, prior to disruption, encodes a porcine α-1,3 galactosyltransferase with an amino acid sequence of SEQ ID NO:10 and] wherein the disruption is by insertion of an exogenous sequence into said gene such that the disruption prevents expression of functional α-1,3 galactosyltransferase.

Please add claims 78-81:

--78. The host cell of claim 2, wherein said wash is in 0.05 x SSC and 0.1% SDS at 65°C.

79. The porcine α-1,3 galactosyltransferase of claim 3, wherein said wash is in 0.05 x SSC and 0.1% SDS at 65°C.

80. The DNA construct of claim 46, wherein the gene, prior to disruption, encodes a porcine α-1,3 galactosyltransferase with an amino acid sequence of SEQ ID NO:10.

81. The method of claim 51, wherein the gene, prior to disruption, encodes a porcine α-1,3 galactosyltransferase with an amino acid sequence of SEQ ID NO:10.--